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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,113	12/20/2001	Kenneth Ouriel	CCF-5814	3220
26294	7590	10/08/2004		
TAROLLI, SUNDHEIM, COVELL & TUMMINO L.L.P. 526 SUPERIOR AVENUE, SUITE 1111 CLEVEVLAND, OH 44114			EXAMINER THALER, MICHAEL H	
			ART UNIT 3731	PAPER NUMBER

DATE MAILED: 10/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/028,113

Applicant(s)

OURIEL ET AL.

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) 68-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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Claims 68-75 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 5.

Claims 1-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, line 3-5, "means for laterally supporting said first end substantially along the length of the central lumen" is confusing and is not understood. It is not seen how the first end can be supported substantially along the length of the central lumen. Claim 21 is indefinite for the same reason.

Claims 1-3, 5-7, 9-11, 41-45, 47 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Kornberg (4,617,932). Kornberg, in figure 1, shows first end (the top end as shown in the figure) having means 16 for laterally supporting the first end comprising a radially expandable support member (col. 4, lines 8-17 and col. 6, lines 31-40), furcated second end (the bottom end as shown in the figure) including at least two branches, each of the two branches including a longitudinal support means 12, the furcated second end being substantially free of an expandable support member and anchoring means 14

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(col. 4, lines 38-42). The phrase "means for laterally supporting said first end substantially along the length of the central lumen" in claim 1, line 3-5, is confusing and is not understood as set forth above. As to claim 41, radially expandable support member 16 extends substantially along the length of the trunk portion. Claim 41 does not specify how far along the length of the trunk portion the radially expandable support member extends. The support member 16 extends for a short distance along the length of the trunk portion and thus meets this limitation, as broadly claimed. As to claims 6 and 44, ring 16 is a self-expanding stent.

Claims 4, 8, 12-14, 46 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kornberg (4,617,932) in view of Pinheiro (5,851,228). As to claim 4, for example, Kornberg fails to disclose that the polytetrafluoroethylene (col. 3, lines 30-31) is expanded. However, Pinheiro teaches that polytetrafluoroethylene used in a graft should be expanded apparently to provide a strong and flexible graft. It would have been obvious to make the polytetrafluoroethylene of the Kornberg graft expanded so that it too would have this advantage. As to claim 8, for example, Kornberg fails to disclose that each of the two branches has a substantial equal length. However, Pinheiro teaches that each of the two branches

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of a furcated graft should have a substantial equal length apparently to accommodate the particular anatomy of a patient. It would have been obvious to make length of each of the two branches of the Kornberg graft substantially equal so that it too would have this advantage. As to claim 12, for example, Kornberg fails to disclose the anchoring means 14 as being a bare stent. However, Pinheiro teaches that anchoring means to secure a graft within a blood vessel should be a bare stent 20a with barbs 25 to positively secure the graft to the blood vessel (col. 4, lines 29-44). It would have been obvious to make the anchoring means of the Kornberg graft a bare stent so that it too would have this advantage.

Claims 15-17, 19, 20, 50-52, 55, 57, 58-63, 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kornberg (4,617,932) in view of White et al. (6,099,558). As to claim 15, for example, Kornberg fails to disclose outflow limbs. However, White et al. teach that outflow limbs 10a, 10b should be attached to a bifurcated stent/graft 10 apparently in order to obtain the advantages of facilitating easy deployment of the prosthesis (since components of the graft assembly can be deployed separately) and insuring that the flow passageways within the assembly reach the ileac arteries (col. 4, lines 10-14, col. 4, line 64 to col. 5, line 5 and col. 8, lines 16-48).

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It would have been obvious to including outflow limbs with the Kornberg bifurcated stent/graft so that it too would have these advantages. As to claim 17, White et al. fail to disclose barbs on the outflow limbs. However, the primary reference Kornberg discloses barbs on the prosthesis to secure it in place. When including outflow limbs on it, it would have been obvious to include barbs on the outflow limbs so that these portions as well would be positively secured to their respective blood vessels. As to claim 57, Kornberg fails to disclose the stent 16 extending substantially the length of the trunk portion. However, White et al. teach that the means for radially supporting a trunk portion of a furcated graft should be a stent (i.e. stent assembly at 17) which extends substantially (nearly) the length of the trunk portion (figure 7i, for example). This arrangement has the advantage of providing support for the trunk portion of the graft throughout most of its length to prevent collapse thereof. It would have been obvious to include a similar stent on the Kornberg graft so that it too would have this advantage.

Claims 18, 53 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kornberg (4,617,932) in view of White et al. (6,099,558) as applied to claims 15, 50 and 61 above, and further in view of Goicoechea et al. (6,051,020). White et al.

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fail to disclose a taper on the outflow limbs where they connect with the branches of the trunk portion. However, Goicoechea et al. teach that the ends of outflow limbs and other vascular graft members (e.g. at 40 or 72) should be tapered (at 42 or 82) in order to facilitate connection with other grafts or natural vessels (col. 11, lines 45-49 and col. 12, lines 12-15). It would have been obvious to make the ends of the White et al. outflow limbs (incorporated into the Kornberg device) tapered so that it too would have this advantage.

Claims 21-23, 25-27 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kornberg (4,617,932) in view of Wisselink (5,984,955). Kornberg fails to disclose at least three branches. However, it was well known in this art to provide at least three branches in grafts so that various blood vessels may be connected. For example, Wisselink teaches that at least three branches may be provided in grafts so that various blood vessels may be connected (figures 1 and 1a). It would have been obvious to provide at least three branches in the Kornberg graft so that it too would have this advantage.

Claims 24, 28, 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kornberg (4,617,932) in view of Wisselink (5,984,955) as applied to claims 21-23, 25-27 and 29-

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31 above, and further in view of Pinheiro (5,851,228) for the reasons set forth in the paragraphs above.

Claims 35-37, 39, 40, 56 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kornberg (4,617,932) in view of Wisselink (5,984,955) as applied to claims 21-23, 25-27 and 29-31 above, and further in view of White et al. (6,099,558) for the reasons set forth in the paragraphs above.

Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kornberg (4,617,932) in view of Wisselink (5,984,955) and White et al. (6,099,558) as applied to claim 35 above, and further in view of Goicoechea et al. (6,051,020) for the reasons set forth in the paragraphs above.

Applicant's arguments filed July 28, 2004 have been fully considered but they are not persuasive for the reasons set forth above. Further, as to claim 57, although Kornberg discloses a ring 16, it does not extend substantially the length of the trunk portion. However, White et al. teach that the means for radially supporting a trunk portion of a furcated graft should be a stent (i.e. stent assembly at 17) which extends substantially (nearly) the length of the trunk portion (figure 7i, for example). This arrangement has the advantage of providing support for the trunk portion of the graft throughout most of its length to prevent collapse thereof. It would have



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been obvious to include a similar stent on the Kornberg graft so that it too would have this advantage, thus insuring that the Kornberg graft also would not collapse. As to claim 21, for example, the Wisselink branches extend from an intersection of the furcated end, as claimed. The intersection is located, in figure 1a for example, at the center of the cross-shaped graft. The claimed trunk portion is the top portion of member 12 (at the top of the cross-shaped graft). One of the claimed three branches is the bottom portion of member 12 (at the bottom of the cross-shaped graft). The other two of the claimed three branches are at 16, 16 (at the sides of the cross-shaped graft).

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (703)308-2154. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht  
10/6/04



MICHAEL THALER  
PRIMARY EXAMINER  
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